



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0626; FRL-9391-2]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances and modifies existing tolerances for residues of acetamiprid in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0626, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0626 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0626, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8147) by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide, acetamiprid, (1E)-N-[(6-chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethananimidamide, including its metabolites and degradates, in or on corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, forage at 15 ppm; and corn, sweet, stover at 30 ppm. The petition also proposed increasing the existing tolerances in fat, meat, and meat byproducts of cattle, goat, horse, and sheep, and milk. Tolerances in cattle, goat, horse, and sheep meat are proposed at 0.30 ppm; cattle, goat, horse, and sheep fat at 0.20 ppm; cattle, goat, horse, and sheep meat byproducts at 0.70 ppm; and milk at 0.30 ppm. That document referenced a summary of the petition prepared by Nisso America Incorporated, the registrant, which is available in the docket, <http://www.regulations.gov>.

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL-9364-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8060) by Nippon Soda Co., Ltd. c/o

Nisso America Inc., 88 Pine St., 14th Fl., New York, NY 10005. The petition requested that 40 CFR 180.578 be amended by increasing the existing tolerances for residues of the insecticide, acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, including its metabolites and degradates, in or on the citrus fruit crop group 10-10 at 1.0 ppm; and citrus, dried pulp at 2.4 ppm. That document referenced a summary of the petition prepared by Nisso America Incorporated, the registrant, which is available in the docket, <http://www.regulations.gov>.

There were no comments received in response to either notice of filing.

Based upon review of the data supporting the petition, EPA has determined that the existing tolerance for dried citrus pulp does not need to be increased. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetamiprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetamiprid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetamiprid is moderately toxic in acute lethality studies via the oral route of exposure and is minimally toxic via the dermal and inhalation routes of exposure. It is not an eye or skin irritant, nor is it a dermal sensitizer. Acetamiprid does not appear to have specific target organ toxicity. Generalized toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency in all species tested. Generalized liver effects were also observed in mice and rats (hepatocellular vacuolation in rats and hepatocellular hypertrophy in mice and rats); the effects were considered to be adaptive. Other effects observed in the oral studies include amyloidosis of multiple organs in the mouse oncogenicity study, tremors in high dose females in the mouse subchronic study, and microconcretions in the kidney papilla and mammary

hyperplasia in the rat chronic/oncogenicity study. No effects were observed in a dermal toxicity study in rabbits.

In the rat developmental study, fetal shortening of the 13th rib was observed in fetuses at the same dose level that produced maternal effects (reduced body weight and body weight gain and increased liver weights). In the developmental rabbit study, no developmental effects were observed in fetuses at doses that reduced maternal body weight and food consumption. In the reproduction study, decreased body weight, body weight gain, and food consumption were observed in parental animals while significant reductions in pup weights were seen in the offspring in both generations. Also observed were reduction in litter size, and viability and weaning indices among F₂ offspring as well as significant delays in the age to attain vaginal opening and preputial separation. In the developmental neurotoxicity study, parental effects were limited to decreased body weight and body weight gains, while the offspring effects noted were decreased body weights and body weight gains, decreased pre-weaning survival (post-natal days (PNDs) 0-1), and decreased maximum auditory startle response in males on PNDs 20 and 60.

In the acute neurotoxicity study, male and female rats displayed decreased motor activity, tremors, walking and posture abnormalities, dilated pupils, coldness to the touch and decreased grip strength and foot splay at the highest dose tested (HDT). There was a decrease in the auditory startle response in male rats at the HDT in the developmental neurotoxicity study; additionally, tremors were noted in female mice at the HDT in the subchronic feeding study.

In four week immunotoxicity studies performed in both sexes of rats and mice, no effects on the immune system were observed up to the highest dose, although significant reductions in body weight and body weight gain were noted at that dose.

Based on acceptable carcinogenicity studies in rats and mice, EPA has determined that acetamiprid is “not likely to be carcinogenic to humans.” The classification is based on (1) the absence of an increase in the incidence of tumors in a mouse carcinogenicity study; and (2) in a rat chronic/carcinogenicity study, the absence of a dose-response and the lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high- dose groups with the controls (although the incidence exceeded the historical control data from the same laboratory, it was within the range of values from the supplier). There was no clear evidence of a mutagenic effect. Acetamiprid tested positive as a clastogen in an *in vitro* study but not in an *in vivo* study.

Specific information on the studies received and the nature of the adverse effects caused by acetamiprid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “*Acetamiprid: Human Health Risk Assessment for the New Use on Sweet Corn and Increased Tolerance on Citrus*” on pages 27-32 in docket ID number EPA-HQ-OPP-2012-0626.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below

which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for acetamiprid used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Acetamiprid for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 10 mg/kg/day UF _A = 10x	Acute RfD = 0.10 mg/kg/day	Co-critical studies Developmental Neurotoxicity in rat

	$UF_H = 10x$ $FQPA\ SF = 1x$	$aPAD = 0.10$ $mg/kg/day$	$LOAEL = 45\ mg/kg/day$ based on decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males. Acute Neurotoxicity Study in rat $LOAEL = 30\ mg/kg/day$ based on decreased locomotor activity
Chronic dietary (All populations)	$NOAEL = 7.1$ $mg/kg/day\ UF_A = 10x$ $UF_H = 10x$ $FQPA\ SF = 1x$	$Chronic\ RfD = 0.071$ $mg/kg/day$ $cPAD = 0.071$ $mg/kg/day$	Chronic Toxicity/Oncogenicity Study in rats $LOAEL = 17.5\ mg/kg/day$ based on decreased body weight and body weight gains in females and hepatocellular vacuolation in males.
Short- and Intermediate-Term Incidental Oral (1-30 days and 1-6 mo.)	$NOAEL = 10$ $mg/kg/day\ UF_A = 10x$ $UF_H = 10x$ $FQPA\ SF = 1x$	$LOC\ for\ MOE = 100$	Developmental Neurotoxicity in rat $LOAEL = 45\ mg/kg/day$ based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.

Short- and Intermediate-term Dermal (1-30 days, 1–6 mo.)	Oral study NOAEL = 10 mg/kg/day dermal absorption rate = 10% $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Developmental Neurotoxicity in rat LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.
Short- and Intermediate-term Inhalation (1-30 days, 1–6 mo.)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%) $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Developmental Neurotoxicity in rat LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0-1, and decreased startle response on PND 20/60 in males.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for acetamiprid. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues in the assessment. Empirical processing factors were used for processed commodities unless such data were not available, in which case DEEM default processing factors from Version 7.81 were used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 USDA NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance level residues in the assessment. Empirical processing factors were used for processed commodities unless such data were not available, in which case DEEM default processing factors from Version 7.81 were used.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that acetamiprid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for acetamiprid. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of acetamiprid for acute exposures are estimated to be 95.2 parts per billion (ppb) for surface water and 0.035 ppb for ground water and for chronic exposures are estimated to be 26.6 ppb for surface water and 0.035 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 95.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acetamiprid is currently registered for the following uses that could result in residential exposures: Indoor and outdoor residential settings, including crack and crevice and mattress treatments. EPA assessed residential exposure using the following assumptions: Exposure for adults (from short-term dermal and inhalation exposure) applying crack and crevice and mattress treatments; and post-application exposure for adults (from short- and intermediate-term dermal and inhalation exposure) and for children 3-6 years old (from short- and intermediate-term dermal, inhalation and hand-to-mouth exposure) following crack and crevice and mattress treatments.

In the previous risk assessment for acetamiprid, EPA had concluded that a subchronic inhalation study was required, and an additional 10X FQPA factor was retained as a database uncertainty factor, which raised the LOC to 1,000 for inhalation scenarios. Because the LOC values were different (i.e. dermal and oral LOC = 100, while inhalation LOC = 1,000) the respective risk estimates were combined using the aggregate risk index (ARI) approach. Since then, however, this conclusion was reevaluated based on a request from the registrant, and EPA has now concluded that this study is not required. Please refer to section D.3.i for further details on this inhalation study requirement conclusion. Therefore, the risk estimates utilize the combined MOE approach, as opposed to the ARI approach.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *<http://www.epa.gov/pesticides/cumulative>*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA

either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicology database for acetamiprid includes rat and rabbit developmental toxicity studies, a 2-generation reproduction toxicity study in rats, and a DNT study in rats. There was no evidence of quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to acetamiprid in the developmental toxicity studies. However, both the developmental neurotoxicity and 2-generation reproduction studies showed an increase in qualitative susceptibility of pups to acetamiprid. Effects in pups in the reproduction study included delays in preputial separation and vaginal opening, as well as reduced litter size, decreased pup viability and weaning indices; offspring effects observed in the developmental neurotoxicity study included decreased body weight and body weight gains, decreased pup viability and decreased maximum auditory startle response in males. These effects were seen in the presence of less severe maternal toxicity (decreased body weight and body weight gain). No evidence of increased quantitative susceptibility was observed in the studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicology data base is complete and acceptable guideline studies for developmental, reproductive toxicity, neurotoxicity (including DNT) and immunotoxicity are available.

In determining the need for a subchronic inhalation study, EPA's weight of evidence decision process included both hazard and exposure considerations as well as incorporation of a presumed 10X Database Uncertainty Factor (UFdb) for the lack of this study. Thus, the Agency's Level of Concern in the weight of the evidence evaluation for inhalation exposure risk assessment is a Margin of Exposure (MOE) of 1,000, which includes the 10X inter-species extrapolation factor, 10X intra-species variation factor, and the 10X UFdb. The Agency had previously determined that the required 21/28-day inhalation study in rats was needed to address data uncertainties related to potential inhalation risk primarily associated with occupational exposure, which presented the scenarios with the highest potential inhalation exposure. After reconsideration, EPA has determined that the inhalation study is no longer required, primarily because exposure levels are expected to be lower than previously anticipated, and residential exposures are expected to be very low. In fact, for residential, non-dietary exposures, the use of an oral Point of Departure (POD) resulted in MOEs higher than the LOC of 1,000. This indicates that the lack of an inhalation study does not reduce the overall confidence in the risk assessment or result in an uncertainty (i.e., the study will not provide a POD sufficiently low to result in a risk of concern). Additionally, in the case of acetamiprid, the oral POD is based on a very sensitive endpoint (effects in rat pups) seen in a developmental neurotoxicity study. Therefore, there is high confidence that the Agency is not underestimating risks in the absence of this study. Because EPA's decision to waive the study essentially incorporates an additional 10X UFdb (i.e. the study was only waived because risks were at least 10X lower than required by use of the inter- and

intraspecies safety factors), a second additional 10X FQPA SF is not being retained for the protection of infants and children.

ii. Acetamiprid produced signs of neurotoxicity in the high dose groups in the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the effects observed in the toxicity studies. The doses and endpoints selected for risk assessment are protective and account for all toxicological effects observed in the database.

iii. No quantitative or qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in either the developmental toxicity study in rats or rabbits. Although increased qualitative susceptibility was seen in the reproduction toxicity and the DNT study, the degree of concern for the effects is low. There are clear NOAELs for the offspring effects and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility. The endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

iv. The exposure databases (dietary food, drinking water, and residential) are complete and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk to infants or children. The dietary exposure assessments were based on tolerance level residues and assumed 100 PCT. Empirical processing factors were used for processed commodities unless such data were not available, in which case the Dietary Exposure Evaluation Model (DEEM) default processing factors were used. EPA made

conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to acetamiprid in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acetamiprid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetamiprid will occupy 68% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 60% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acetamiprid is not expected.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to acetamiprid.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 330 for adults and 120 for children. Because EPA's level of concern for acetamiprid is an MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acetamiprid is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology Liquid chromatography with tandem mass spectrometry (LC-MS/MS), Method #KP-216R0 and its variant #KP-216R1 is available to enforce the tolerance expression. The method may be requested from: Chief,

Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address:

residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no established Codex MRLs for acetamiprid on sweet corn. There are Codex MRLs on livestock commodities, with the revised livestock tolerances for the U.S. being higher than the Codex values. Given the revised use pattern including sweet corn, these higher U.S. livestock commodity tolerances are warranted. However, this is not considered to be a significant trade irritant, as livestock commodities are rarely shipped internationally. With the citrus (crop group 10-10) tolerance increase to 1.0 ppm, the U.S. will be harmonized with Codex MRLs.

C. Revisions to Petitioned-For Tolerances

For citrus, dried pulp, based on a review of the residue data, the Agency has determined that a revised citrus pulp tolerance is not needed and that the existing tolerance of 1.2 ppm is adequate.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, including its metabolites and degradates, in or on corn, sweet, forage at 15 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; and corn, sweet, stover at 30 ppm. In addition, existing tolerances are increased as follows: Cattle, fat at 0.20 ppm; cattle, meat at 0.30 ppm; cattle, meat byproducts at 0.70 ppm; fruit, citrus, group 10-10 at 1.0 ppm; goat, fat at 0.20 ppm; goat, meat at 0.30 ppm; goat, meat byproducts at 0.70 ppm; horse, fat at 0.20 ppm; horse, meat at 0.30 ppm; horse, meat byproducts at 0.70 ppm; milk at 0.30 ppm; and sheep, fat at 0.20 ppm; sheep, meat at 0.30 ppm; sheep, meat byproducts at 0.70 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health

Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 13, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.578 is amended as follows:

- i. In paragraph (a)(1), add alphabetically the commodities “corn, sweet, kernel plus cob with husks removed,” “corn, sweet, forage,” “corn, sweet, stover” to the table; and revise the entry for “fruit, citrus, group 10-10” .

- ii. In paragraph (a)(2), revise the entries for and “cattle, fat”, “cattle, meat”, “cattle, meat byproducts”; goat, fat”, “goat, meat”, “goat, meat byproducts”; “horse, fat”, “horse, meat”, “horse, meat byproducts”; “milk”; and “sheep, fat”, “sheep, meat”, and “sheep, meat byproducts”.

The additions and revisions read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* *	* * *
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, forage	15
Corn, sweet, stover	30
* *	* * *
Fruit, citrus, group 10-10	1.0
* *	* * *

(a)(2) * * *

Commodity	Parts per million
Cattle, fat	0.20
Cattle, meat	0.30
Cattle, meat byproducts	0.70
* *	* * *
Goat, fat	0.20
Goat, meat	0.30
Goat, meat byproducts	0.70
*****	*****
Horse, fat	0.20
Horse, meat	0.30

Horse, meat byproducts	0.70
Milk	0.30
*****	*****
Sheep, fat	0.20
Sheep, meat	0.30
Sheep, meat byproducts	0.70
* * * * *	

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